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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,194	10/28/2003	Denis Francois Hochstrasser	108140.00030	4418
38485	7590	12/26/2008	EXAMINER	
ARENT FOX LLP			SWARTZ, RODNEY P	
1675 BROADWAY			ART UNIT	
NEW YORK, NY 10019			PAPER NUMBER	
			1645	
			NOTIFICATION DATE	
			DELIVERY MODE	
			12/26/2008	
			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

NYIPDocket@arentfox.com

Patent\_Mail@arentfox.com

### Office Action Summary

**Application No.**

10/695,194

**Applicant(s)**

HOCHSTRASSER ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-38 and 40-47 is/are pending in the application.
- 4a) Of the above claim(s) 20, 23-28 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-19, 21, 22, 29-38, 40-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6, 8-38 and 40-47 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 12 September 2008, is acknowledged.
2. Claims 1-6, 8-38, and 40-47 are pending. Claims 20, 23-28, and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.
3. Claims 1-6, 8-19, 21, 22, 29-38, and 40-46 solely drawn to a method and kit for diagnosis of TSE using polypeptide are under consideration.

#### **Rejection Maintained**

4. The rejection of claims 29-31 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of "probe", is maintained.

Applicants argue that "probe" is described in the specification, paragraph 00044, as a probe that "may consist" of a strip having several absorbent wells and "may have" hydrophobic, strong anionic or weak cationic exchange surfaces under condition which allow binding polypeptides.

The examiner has considered applicants' argument, but does not find it persuasive. The cited paragraph, which giving an example, does not define what the metes and bounds are for a "probe".

5. The rejection of claims 1-6, 8-19, 21, 22, 29-38, and 40-46 under 35 U.S.C. 112, first paragraph, scope of enablement for differentiation of any/all forms of TSE by mere alteration of level of nonspecified proteins, is maintained.

Applicants argue that claims 2, 3, 12-15, 32, 33, 35-37, 40 and 43 recite that the reference amount is specifically described as being present in the body fluid of a subject that either does, or in some cases, does not have BSE or CJD and therefore the rejection does not apply to these claims.

The examiner has considered applicants' argument, but does not find it persuasive. Claim 1 recites that "wherein an increase or decrease in the polypeptide in the subject's body fluid compared to the reference indicates BSE or CJD in the subject". In the embodiment of group C, it is put forth that a hemoglobin fragment is indicative of BSE or CJD. However, it remains unclear how one distinguishes BSE or CJD samples from a normal subject's sample of serum or plasma which would also contain hemoglobin fragments.

Applicants argue that one skilled in the art would understand that the size of signal of the protein peaks is compared with diseased and healthy samples to identify the discriminatory species.

The examiner has considered applicants' argument, but does not find it persuasive for the reasons put forth in the original rejection. In addition, the claims do recite that the discrimination is dependent on the size of the signal, only that an "increase or decrease" in the polypeptide is indicative. There remains no cut-off values for discriminating between diseased and healthy subjects.

### **Conclusion**

6. No claims are allowed.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 20,23-28 and 47 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

December 18, 2008